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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,126	01/12/2001	Kazuhiro Tsujita	Q61243	8903

7590

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT PAPER NUMBER

3737

DATE MAILED: 03/24/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/758,126

Applicant(s)

TSUJITA ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 16-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## FINAL ACTION

### *Response to Arguments*

1. Applicant's arguments filed on 12/22/03 have been fully considered but they are not persuasive. The Applicant's Representative in page 16 addresses the rejections by stating that there is specification support for creating a fluorescence image and a reflectance image. The issue is how are the multiple fluorescence images and the reflectance image, manipulated to arrive to the claimed tissue image. There is no specification support to arrive to this tissue image, nor to the arguments clarify the rejections raised. Therefore, the rejections are maintained and made final.

### *Specification*

2. The following is a quotation of 37 CFR 1.71 (a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

3. The specification is objected to under 37 CFR 1.71 because the process and structure of displaying a fluorescence image throughout the specification lacks any additional explanation and understanding as to a proper interpretation of the claims. It is unclear as to how the tissue

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condition image is related to the first fluorescence image and at least one of a second fluorescence image and a reflected reference image. Are the first and second fluorescence and reference reflected images combined, subtracted, correlated, superimposed, etc to arrive at the tissue image. The structure and the process to arrive at the tissue image with respect to all the disclosed images should be clarified.

In addition it is confusing and unclear as to how the terms "accurate" and "inaccurate" in page 25 are being used to convey the condition of the tissue. Further confusion is added with the recitation of line 16-18, because how can an accurate and inaccurate tissue image provide a tissue condition image to be seen with a high reliability. Further page 5 lines 8-14 regularly reflected light is interpreted as the reference reflected light. But in latter in page 25 lines 19-24, applicant defines the two as different reflected light components. This is inconsistent with the previous recitation.

The disclosure as a whole appears to be a direct translation of a foreign document, therefore it is very confusing and unclear to what is being disclosed. The language of the specification lacks to fully disclose the invention.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-15 and 33-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification

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provides insufficient disclosure to enable an understanding of what is being claimed. It is unclear as to how the tissue condition image is related to the first fluorescence image and at least one of a second fluorescence image and a reflected reference image. Are the images combined, subtracted, correlated, superimposed, etc to arrive at the tissue image. The steps should comprise the processing to arrive at the tissue image with respect to all the disclosed images rather than the determination of abnormal tissue. In every diagnostic system it's inherent that the end goal is diagnosis of abnormal tissue condition. To reiterate it is one of skill in the art is not enabled to replicate the invention because it is unclear as to what the tissue condition image is referring to and how it is related to the three different images. The claims are confusing because one is left to decipher whether the tissue image is an addition, subtraction, correlation, superposition, of one or more of the first fluorescence image and at least either of the second fluorescence image and a reflected reference light image. Further it is not enabling as to how the tissue image provides for the display of the fluorescence image as claimed.

Based on the manner in which the claims are written it is impossible to determine the scope of the invention. Therefore no prior art rejection is given for the claims.

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM